December 27, 1999
210 Monte Diablo #303
San Mateo, CA 94401

Dr. Jane E. Henney, Commissioner
Food and Drug Administration
5600 Fishers Lane, rm. 14-71
Rockville, MD 20857

2002 '00 JAN -5 P2:00

Docket Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Docket No. 97N-484S

Dear Dr. Henney,

As you know, the FDA has proposed new regulations for reproductive tissue donation. On it's face it appears to be health and safety regulations designed to protect public health, a laudable goal. However, the effect of this proposal, as presently worded, would be so odious as to remind the public of the United States Public Health Service's most evil enterprise, the Tuskegee Syphilis Experiment, and bring to mind to many Americans, especially Jewish Americans, an evil that the Third Reich perpetrated on it's own citizens, forced sterilization. Some may think this statement hyperbole until one realizes that these regulations would make it almost impossible for gay men to have children. Most who saw our May 17, 1999 press release, signed by myself, the ACLU of Northern California, the Sperm Bank of California, the National Center for Lesbian Rights, and the Gay and Lesbian Medical Association, which began, "The Food and Drug Administration is trying to prevent gay men from having children," thought it too fantastic to be true. But **ALL** who have investigated it have, sadly, found it to be all too true. I had voiced my concern about these pending regulations to the your agency and the CDC via letters and phone conversations for over three years prior to their publication. I have tried to engage the FDA in a discussion of the scientific facts and the safety procedures already in place in the sperm banking industry. However, because your agency is not required to operate under appropriate public scrutiny, as the sunshine laws enacted in many states requires their health departments to operate, my concerns were ignored and the process proceeded in secret. The result is a document which ignores current scientific evidence and inappropriately scapegoats gay men by excluding them from the possibility of medically assisted conception. On May 7, 1996 Tom Spira, M.D., Assistant Chief for Medical Science for the CDC, said, "I would not, categorically, want to exclude them (gay men) since we have appropriate testing. If you do so, I believe, you gain a false sense of security." In light of the fact that those writing the FDA's proposed regulations were aware of Dr. Spira's statement and why he made it, this proposal is a deliberate attempt to mislead the public.

As part of the notice and comment period about these proposed regulations the FDA has received many polite suggestions and researched, thoughtful comments

97N 484S

C400

from lawyers, health care professionals involved in sperm banking and citizens whom these regulations would affect. However, behind all of the polite comments is a seething anger and disgust that the FDA would proceed in such an outrageous fashion. If the FDA tries to enact these proposals without incorporating the appropriate changes suggested by the multiplicity of letters you have received, I can unequivocally state that many of us, including myself, will not rest until the regulations are voided and those responsible are called to account for trying to force their bigotry, masquerading as science, on the public. If unchanged, all those responsible for the implementation of these regulations will be guilty of a hate crime. We will go to court to stop you and everyone watching Court TV will see how FDA "scientist" turned their white coats into pointed white sheets. Court TV has already contacted us and said they are anxious to broadcast such a trial. Progressive elements in the Jewish community will speak out against the FDA's proposal of mass sterilization via regulation. If unaltered these regulations will be a personal attack on the reproductive rights of millions of Americans. Therefore, the resulting fight will be very public, very ugly and be very a personal attack on your agency and those in your agency who have proposed it and defended it. This is a promise.

In formulating these regulations the FDA deliberately ignored commonly accepted and well documented current scientific knowledge. In ignoring current knowledge the FDA would prevent millions of gay and lesbian Americans from being able to access fertility services in our medical care system and would substitute it's judgment for the personal and intimate decisions as to how many citizens, both heterosexual and homosexual, choose to conceive. In it's attempt to defend these proposals the agency has lied to the press, to the Department of Health and Human Services and to congressional staff members. And it has circumvented the usual departmental review process before publishing this proposed regulation in the Federal Register.

As you should be aware by now, reproductive tissue is unique because, unlike blood and organs, anonymous sperm donations are frozen and quarantined for six months. This is twice the usual window period that it takes for HIV infection to appear on an HIV antibody test. Current scientific evidence supports that the HIV antibody test is an excellent test for detecting infection within three months of exposure. The Centers for Disease Control reports only one case of an otherwise healthy man going beyond this window period (Morbidity and Mortality Weekly Report 1996; 45: 181-185) however, he was positive for HIV infection on the p24 antigen test. This case was a heterosexual man, infected by his wife, who did not have any CDC defined "risk factors" for relevant communicable diseases. He had no homosexual contact and did not use injectable drugs. In the FDA's proposed regulation, however, rather than mandating that all donors be tested using both the HIV antibody test and the p24 antigen test as this case would suggest, it bars sperm donors with "risk factors". The proposal declines to define what "risk factors" are and states that such a definition would follow in a guidance document. I am hopeful that the FDA will take to heart the many suggestions they are receiving and not exclude gay sperm donors, whom the FDA describes as "men who have sex with men (MSM)". However, it is very disturbing that the FDA has already made repeated public statements, to the press and at it's own public forums, that MSM's are defined as donors with "risk factors" and will be barred from the potential sperm donor pool. The FDA has presented no evidence that such an action would increase safety.

Instead it bring out epidemiological "evidence" of the high incidence of HIV among MSM's to support their position despite the fact that appropriate testing and quarantine makes this information irrelevant to reproductive tissue. Indeed, at the FDA's Blood Products Advisory Committee of December 11, 1997 which discussed loosening blood donation restrictions on MSM's, in his background and introduction Andrew Dayton, M.D., Ph.D., spoke of a "two-phase testing scenario". He said that if blood banks were to adopt this scenario that "this would basically have the effect of dropping the (HIV) prevalence problem to zero." Dr. Dayton's suggestion is already standard practice in sperm banking facilities. Many women, mostly lesbians, who seek to purchase sperm are specifically seeking gay donors. This proposed regulation would exclude their choice without sound scientific reason. Testing and quarantine safeguards are already are in place. The one case of non-seroconversion who would have been identified by the p24 antigen test would not have been barred under this proposal. Yet, because of this one heterosexual man and irrelevant epidemiology, MSM's are barred from the sperm donor pool. This would be laughable if it were not true.

Secondly, the proposal mandates that a directed donor's sperm be frozen and quarantine for six months prior to use. This is a gross intrusion into the private decision making process of citizens seeking fertility assistance. The scientific literature is clear on this issue. The freezing process is extremely deleterious to sperm. This proposal would, if followed, render most men "sterile" forcing unnecessary and expensive in vitro fertilization as their only option. Also clear in the medical literature is the fact that pregnancy rates are much lower using frozen semen rather than fresh semen. Illustrative of the difficulty this proposal would cause is the case of a married couple with severe fertility problems. He was completely sterile and she, at 42, also had severe fertility problems. They asked the husband's brother if he would donate sperm for them. As he lived a far distance away they sought to freeze his sperm for convenience sake. Unfortunately, the brother's sperm had very poor cryosurvival, but, he was willing to make the long trip every month to help his brother and sister-in-law start a family. Under these regulations the FDA would say to this family that the United States government will not allow them to do this. Even if his sperm had survived the freezing process, the FDA would have mandated that this 42 year old woman wait six months before attempting conception. Why does the FDA think it is appropriate to stop this family from making the very difficult and personal decision as to how they wish to have children?

The effect this proposal would have on lesbians and gay men seeking fertility assistance would be devastating. Knowing that most men would be barred from seeking standard fertility services more and more would try unsupervised, untested, and unsafe home inseminations. Gay men with low sperm counts and/or those with poor cryosurvival would have little hope of using their sperm for successful intrauterine inseminations. Lesbians who have fertility problems and wishing to have a child with a gay friend would be denied the increased chance of conception using fresh insemination. Mandating safeguards for screening, counseling and informed consent would be reasonable and proper. California's Health and Safety Code 1644.5 does exactly that. Through these proposed regulations the FDA would dictate to women whom they may and may not attempt conception with. Through

these proposed regulations the FDA would bar gay men from accessing fertility services. This unfounded control over people's private lives will not to be tolerated.

It is disgusting that the FDA has been misleading HHS, congressional staff members and the press about the process of producing this proposal and about scientific information relating to this proposal. When the FDA first sent this proposal for review to HHS they informed Secretary Shalala's office that there was only minor objections to the proposal which had recently surfaced. However, there was already serious scientific objection to this proposal which included letters and phone calls I had made dating back three years. This only came to light when an article in the Washington Blade alerted HHS to the controversy.

FDA officials have been on a disinformation campaign. They have repeated stated that the freezing process has very little detrimental effect on sperm survival and that most men have sperm that has good cryosurvival despite overwhelming documentation in the medical literature to the contrary. The FDA has failed to produce even one article that supports this contention and the FDA's position contradicts all of the experts in the field who are actually engaged in sperm banking. Similarly, congressional staff members were subjected to the FDA's unsubstantiated claim that the use of frozen sperm does not have a lower pregnancy rate than does fresh sperm. Once again, they failed to produced one shred of evidence supporting their claims in the face of overwhelming evidence in peer reviewed medical journals which documents the opposite.

The FDA is unable to state who is covered by these proposed regulations. Does it only cover sperm banking facilities as FDA officials originally said or does it cover all physician and medical practices as the regulations suggest? One would think that the FDA would know the answer even if it was not clearly stated in the proposal. Yet, the FDA is unsure of this very crucial piece of information about their own proposal. Your agency's only answer was "that FDA is currently considering (the question), and is planning to address through the notice and comment rule making process."

All proposed regulations are reviewed by the HHS General Counsel before they are published in the Federal Register. This process was circumvented and the General Counsel did not have the opportunity to comment on this proposal prior to publication. Had this usual process been followed, it is possible that some of the problems I have detailed here could have been corrected.

With regard to reproductive tissue, the FDA has ignored current scientific knowledge and crafted inappropriate regulations that block freedom of reproductive choice while failing to mandate the use of the p24 antigen test for HIV screening which is both easily accessible and inexpensive. The proposed regulations should be modified to conform with California's Health and Safety Code 1644.5 which specifically allows the use of fresh sperm for insemination with directed donors after appropriate screening and counseling. Additionally, the guidance document defining donors with "risk factors" should exclude MSM's with regard to reproductive tissue that has been frozen and quarantined for six months. Furthermore, the FDA should seek to operate following it's own well established policy reviews process prior to publication.

The FDA Director needs to investigate this wrong doing and reprimand those who deliberately ignored the scientific evidence and misled HHS, congressional staff members and the press. You should make sure these problems are corrected and do not happen again. Additionally, those involved in creating new regulations should be open new information and be open to criticism as to how they may have erred rather than defending their position at the cost of the freedom of choice, public safety and the truth.

I am demanding that the FDA follow the scientific evidence and do the right thing. If you do not, we will do everything we can to shine the spotlight of the media on your agency and this proposal. Your staff's unscientific antics will be rejected and you agency will, rightfully, be subjected to public ridicule once again.

I strongly suggest you read Professor James H. Jones's book, Bad Blood: The Tuskegee Syphilis Experiment. Using the lessons of Tuskegee, his last chapter warns the gay community that the United States Public Health Service will use HIV as an excuse to violate our civil rights. Are you going to try to fulfill Professor Jones's prediction? There is indeed an eerie similarity between referring to African-Americans as "a notorious syphilis soaked race", as the organizers of Tuskegee Experiment did, and referring to gay men as "a group that is high risk for HIV infection". Sixty years has made the pseudo-scientific jargon sound more sophisticated, but the sentiment is still the same old message of hate. Will your watch as director of the FDA be remembered for a similar hate crime as Tuskegee? Will my warnings to you be greeted with the same disregard as Peter Buxton's was until his message about Tuskegee hit the press? Only you can answer that. However, I will remind you that the United States Public Health Service was able to keep Mr. Buxton's alarm bell about Tuskegee quiet for ten years only because Mr. Buxton did not have the internet nor Court TV.

I am a gay Jew who grew up in the post-Holocaust generation. I will not let you do to me and one part of my people what the Nazis tried to do to another part of my people 55 years ago. Never again.

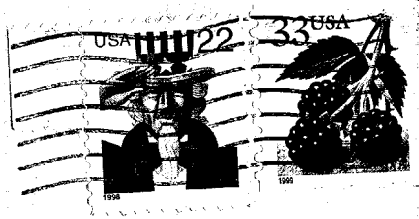
Sincerely,

Leland Traiman

Leland Traiman, RN/FNP

Leland Trainman
Stewart Blandon
210 Monte Diablo Ave. #303
San Mateo, CA 94401

SAN FRANCISCO CA 941
PM
27 DEC
1999



DOCKET MANAGEMENT BRANCH (HFA-305)
FDA
5630 FISHERS LANE, RM 1061
ROCKVILLE, MD 20852